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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,132	10/09/2001	Marc Kolkman	GC636-2	1616

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GENENCOR INTERNATIONAL, INC.  
ATTENTION: LEGAL DEPARTMENT  
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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

17

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/975,132

Applicant(s)

KOLKMAN, MARC

Examiner

Konstantina Katcheves

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nc address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Claims 1-52 are pending in the present application.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22, drawn to a process for enhanced secretion of a polypeptide, classified in class 435, subclass 69.1.
- II. Claim 23, drawn to a method for reducing the susceptibility of a polypeptide to an extracellular protease, classified in class 435, subclass 471.
- III. Claims 24-29, drawn to an expression cassette, classified in class 435, subclass 320.1.
- IV. Claims 30-38, drawn to a recombinant protein, classified in class 530, subclass 350.
- V. Claims 39-44, drawn to a chimeric polypeptide, classified in class 530, subclass 402.
- VI. Claims 45-52, drawn to a nucleic acid construct, classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I and II comprise steps which are not required for or present in the method of the other group. Thus, the operation, function and effects of these different methods are different and distinct from each

Art Unit: 1636

other. Moreover, the end results of each of these methods differ for example: reducing the susceptibility of a polypeptide to an extracellular protease and enhancing secretion of a polypeptide. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Group I and II and Groups III-VI are biologically and functionally different and distinct from each other and thus one does not render the other obvious. Methods of reducing the susceptibility of a polypeptide to an extracellular protease and enhancing secretion of a polypeptide are not used to make the products of Groups III-VI. The operation, function and effects of the Groups I and II are completely different and distinct from the operation, function and effects of the products of Groups III-VI which are expression cassettes, recombinant proteins, chimeric polypeptides and nucleic acid molecules. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

The proteins of Groups IV and V and the expression cassette of Group IV and the nucleic acid of Group VI are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The proteins of Groups IV and V are not required to produce the DNA of Groups VI and IV (the DNA can be replicated in vectors without use of the protein) and the proteins of Groups IV and V are not required to produce the DNA of Groups VI and IV (which can be produced synthetically or isolated from cells). Therefore, the inventions of the two groups are capable of supporting separate patents. Additionally, Groups IV and V differ from each other because the chimeric polypeptide of Group V is a secretion signal peptide, a heterologous polypeptide and a tag sequence while Group IV does not require these elements.

Art Unit: 1636

Groups I, II, IV and VI comprise multiple inventions which are methods and products drawn to different and distinct sequences which do not render obvious each other and thus are patentably distinct. For example, if Group I is elected, Applicant must elect a single invention, which is the method drawn to the use a tags with different charged amino acid residues, which differ functionally, biologically and structurally from each other. The methods and products comprising tags with different charged residues represent unrelated, independent and patentably distinct inventions. Applicant is required to elect one of the distinct inventions set forth in these groups by electing a sequence with a specific charged residue. Additionally, Group IV, claim 38, recites various sequences which themselves are separate and distinct inventions to which Applicant is required to elect a single sequence.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1636

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves  
September 30, 2003



JAMES KETTER  
PRIMARY EXAMINER